12.a. Prescribed drugs. (continued

(8) Generic drugs must be dispensed to recipients if:

(a) the generically equivalent drug is approved and is determined as therapeutically equivalent by the FDA;

(b) in the pharmacist's or dispensing physician's professional judgment, the generically equivalent drug is safely interchangeable with the prescribed drug;

(c) the charge for the substituted generically equivalent drug does not exceed the charge for the drug originally prescribed; and

(d) the practitioner has not written in his or her own handwriting "Dispense as Written-Brand Necessary" or "DAW-Brand Necessary" on the prescription. Effective January 2, 2004, even if the practitioner has written "Dispense as Written-Brand Necessary" or "DAW-Brand Necessary" on the prescription, authorization is required to dispense brand name drugs.

(9) ~~Over the counter medications must be dispensed in the manufacturer's unopened package, except that Sorbitol may be repackaged.~~

~~(10)~~ The following limits apply to drugs dispensed under unit dose packaging:

(a) Dispensing fees for drugs dispensed in unit dose packaging shall not be paid more often than once per calendar month or when a minimum of 30 dosage units have been dispensed, whichever results in the lesser number of dispensing fees.

(b) Only one dispensing fee per calendar month will be paid for each maintenance drug, regardless of the type of unit dose system used or the number of times during the month the pharmacist dispenses the drug.

12.a. Prescribed drugs. (continued)

(c) An additional dispensing fee per prescription shall be paid to pharmacists using an in-pharmacy packaged unit dose system (except for over-the-counter ~~[OTC]~~ medications) approved by the Board of Pharmacy for the return of drugs when dispensing to recipients in a long-term care facility if:

(i) the pharmacy is registered with the Department by filing an addendum to the provider agreement;

(ii) a minimum 30-day supply of the drug is dispensed, although a lesser quantity may be dispensed for an acute course of medication therapy for a specified time period;

(iii) the national drug code from the drug stock container used to fill the unit dose package is identified to the Department;

(iv) the unit dose package containing the drug meets the packaging standards set forth in Minnesota Statutes that govern the return of unused drugs to the pharmacy for reuse and documentation that unit dose packaging meets permeability standards of the Board of Pharmacy; and

(v) the pharmacy provider credits the Department for the actual acquisition cost of all unused drugs that are eligible for return and reuse.

(10) Delivery charges for a drug are not covered.

Drug Formulary:

All drugs and compounded prescriptions made by a manufacturer that are covered under a signed rebate agreement with CMS are included in the drug formulary, with the following limitations on coverage:

12.a. Prescribed drugs. (continued)

(1) Over-the-counter drugs must be listed in the Department's "Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update. The following over-the-counter drugs are covered only when prescribed by a licensed practitioner or a licensed pharmacist who meets standards established by the Department, in consultation with the Board of Pharmacy:

(a) antacids;

(b) acetaminophen;

(c) aspirin;

(d) family planning products;

(e) insulin;

(f) products for the treatment of lice;

(g) vitamins for adults with documented vitamin deficiencies;

(h) vitamins for children under the age of seven and pregnant or nursing women; and

(i) any other drug identified by the Department, in consultation with the Drug Formulary Committee.

(2) The following categories of drugs ~~subject to restriction under §1927(d)(2)~~ are not covered pursuant to §1927(d)(2):

(a) ~~Agents when used for anorexia, except that medically necessary anorectics are covered for recipients previously diagnosed as having pickwickian syndrome and currently diagnosed as having diabetes and being morbidly obese~~ Effective August 1, 2003, drugs used for weight loss, except that medically necessary lipase inhibitors may be covered for recipients with type 2 diabetes.

(b) Agents when used to promote fertility.

12.a. Prescribed drugs. (continued)

(c) Agents when used for cosmetic purposes or hair growth.

(d) Covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(e) Drugs described in §107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of 21 CFR §310.6(b)(1) (DESI drugs)).

(3) The following categories of drugs ~~subject to restriction under §1927(d)(2)~~ are covered with limitations pursuant to §1927(d)(2):

(a) Agents when used for the symptomatic relief of cough and colds must be listed in the Department's "Minnesota Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update.

(b) ~~Nonprescription drugs must be listed in the Department's "Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update.~~

~~(c)~~ Prescription vitamins and mineral products for children, pregnant and nursing women, and recipients with documented vitamin deficiencies. The limitations do not apply to fluoride treatments. Prenatal vitamins are restricted to pregnant and nursing women.

Notwithstanding the above paragraph, some vitamins and mineral products are available for the treatment or prevention of certain diseases:

(1) niacin;

(2) calcium and calcium/vitamin D; and

(3) generic preparations equivalent to Ocuvite.

12.a. Prescribed drugs. (continued)

Prior Authorization:

A. The following requirements, found in §1927(d)(5) of the Act, are met:

- The prior authorization program provides a response by telephone or other telecommunication device within 24 hours of a request

- The prior authorization program provides for the dispensing of at least a 72-hour supply of a covered drug in an emergency situation (except for those drugs that are excluded or restricted from coverage, as noted above)

B. Based on the requirements in §1927, the State has the following policies for the supplemental drug rebate program for Medicaid recipients:

1) The model rebate agreement between the State and drug manufacturers for drugs provided to Medicaid recipients, submitted to CMS on September 30, 2002, and entitled "State of Minnesota Supplemental Rebate Agreement," has been approved by CMS.

2) Supplemental drug rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.

3) A drug that the Department determines comes within its supplemental drug rebate program for Medicaid recipients as allowed by §1927, but for which a manufacturer has not signed a supplemental drug rebate agreement approved by CMS, will be prior authorized.

Even if a manufacturer has not signed a supplemental drug rebate agreement, there is never prior authorization for any atypical antipsychotic drug prescribed for the treatment of mental illness if:

- there is no generically equivalent drug available; and
- the drug was initially prescribed for the recipient before July 1, 2003; or
- the drug is part of the recipient's current course of treatment.

12.a. Prescribed drugs.
Payment is determined in accordance with 42 CFR §§447.331 to 447.333.

- For drugs dispensed by a pharmacy, payment for prescription drugs is the lower of:
  (1) the actual acquisition costs of the drugs, plus a fixed dispensing fee;

  (2) the maximum allowable cost set by the State agency not to exceed in the aggregate the upper limits established under 42 CFR §447.332 for multiple source drugs, plus a fixed dispensing fee; or

  (3) the provider's usual and customary charge to the general public.

- Payment for over-the-counter drugs is at the provider's usual and customary charge to the general public. If the pharmacy is not accessible to, or frequented by, the general public, or if the over-the-counter drug is not on display for sale to the general public, the usual and customary charge is the actual acquisition costs plus a 50 percent add-on based on the actual acquisition cost.

- Effective July 30, 2001, for drugs administered in an outpatient setting, payment for prescription drugs is the lower of:
  (1) 95% of the average wholesale price (wholesale price minus five percent);

  (2) the maximum allowable cost set by the State agency not to exceed in the aggregate the upper limits established under 42 CFR §447.332 for multiple source drugs; or

  (3) the provider's usual and customary charge to the general public.

Effective ~~March 1,~~ July 1, 2003, the State agency establishes the actual acquisition cost to equal ~~86%~~ 88.5% of the average wholesale price (wholesale price minus ~~14~~ 11.5 percent), except when a drug has its wholesale price reduced as a result of the actions of the

12.a. Prescribed drugs.

National Association of Medicaid Fraud Control Units. In that case, the State agency establishes the actual acquisition cost at the reduced average wholesale price, without the ~~14~~ 11.5 percent deduction.

With the following exceptions, the dispensing fee is $3.65 plus an additional $.30 dispensing fee allowed for legend drug prescriptions dispensed using a pharmacy packaging unit-doses blister card system:

(1) The dispensing fee for intravenous drugs which require mixing by the pharmacist is $8.00, except cancer chemotherapy IVS, which is $14.00, unless item (2), below, applies.

(2) The dispensing fee for total parenteral nutrition products which require mixing by the pharmacist is $30.00 for those dispensed in 1 liter quantity, and $44.00 for those dispensed in a quantity greater than 1 liter.

In addition, the State agency will receive a rebate for prescribed drugs in accordance with the manufacturer's contract with the Centers for Medicare & Medicaid Services.